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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,936	04/14/2004	Vahid Saadat	USGINZ00700	7289

40518 7590 01/13/2011  
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EXAMINER
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KASZTEJNA, MATTHEW JOHN

ART UNIT	PAPER NUMBER
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3779

MAIL DATE	DELIVERY MODE
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01/13/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/824,936  
Filing Date: April 14, 2004  
Appellant(s): SAADAT ET AL.

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Johney U. Han  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed December 13, 2010 appealing from the Office action mailed March 3, 2010.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

U.S. Patent Application Publication No. 11/036029

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 1, 2, 5-9, 19, 23, 24, 26, 27, 29-33, 36-38, 40-43 and 65-77 are finally rejected and are the subject of this Appeal.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being

maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

5,251,611	Zehel et al.	10-1993
2005/0096502	Khalili	5-2005

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 31-33, 36-38, 40-43 and 65-77 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2005/0096502 to Khalili.

**In regards to claims 31 and 65**, Khalili discloses an apparatus for obtaining endoluminal access, the apparatus comprising: a substantially flexible elongate body 310 having a working axis and a distal region 308, the elongate body configured for insertion within a body lumen (see paragraph 0078); at least two working lumens 330, 332 extending through the flexible elongate body; at least one articulating element 312-314 disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member 302-304 pivotally connected to a first hinge (not labeled) on the articulating element and a second hinge (not labeled) on the elongate body (see paragraphs 0079-080), wherein the articulating

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element articulates from an in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening 330 of one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position (see Figs. 1a-b and paragraph 0066). Alternatively, the embodiment shown in Figures 15-16 reads on claim 31, wherein it is shown an elongate body having at least one articulatable element 362 *disposed near or at* a distal region thereof into a body lumen; moving the articulatable element from a position in-line with or adjacent to a working axis of the elongate body to a position out-of-line with the working axis, thereby at least substantially exposing a distal opening of a working lumen 360 provided in the elongate body; and passing a diagnostic or therapeutic tool 368 through the working lumen while the articulatable element is maintained in the out-of-line position (see paragraphs 0082-0083).

**In regards to claims 32 and 66,** Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element comprises a visualization element 326 configured to image within a body lumen (paragraph 0079).

**In regards to claims 33, 41 and 70-71,** Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements comprise at least two visualization elements configured to provide stereoscopic visualization (see paragraph 0066).

**In regards to claim 36**, Khalili discloses a method for obtaining endoluminal access, further comprising injecting or withdrawing fluid through the working lumen (see paragraph 0068).

**In regards to claims 37**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the apparatus has a delivery configuration in which the articulating element is aligned with or adjacent to the working axis of the elongate body, and a deployed configuration wherein the articulating element is articulated off-axis from the working axis of the elongate body (see Figs. 1a-d and paragraphs 0009-0016).

**In regards to claims 38 and 40**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the distal opening is covered by the articulating element in the deliver configuration as the articulating element is capable multiple degrees of freedom, thus allowing manipulation of the element in and out of line with the working axis as desired (see Figs. 1a, 8 and paragraphs 0013, 0071).

**In regards to claim 67**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises at least two articulating elements (see Fig. 13a).

**In regards to claims 68-69**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements are configured for independent off-axis articulation or coordinated off-axis articulation (see paragraphs 0050 and 0054).

**In regards to claim 72**, Khalili discloses an apparatus for obtaining endoluminal access, further comprising a visualization element and wherein off-axis articulation of

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the articulating element is configured to expose the visualization element 330 (see Figs. 1a-d, 8 and 13b).

**In regards to claim 73**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least one articulating element is pivotally connected to the elongate body by a pair of pivoting linkage members, with each pair of linkage members being pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body (see Figs. 13a-b and paragraph 0079).

**In regards to claims 42-43 and 74-75**, Khalili on discloses an apparatus for obtaining endoluminal access, wherein the elongate body is steerable and may be rigidizable (see paragraphs 0009-0016, 0044-0045, 0048 and 0084-0087).

**In regards to claim 76**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises a diagnostic tool (see paragraph 0046, 0066 and 0079).

**In regards to claim 77**, Khalili discloses an apparatus for obtaining endoluminal access, further comprising an atraumatic tip 308 (see paragraph 0078).

Claims 1-2, 5-9, 19, 23-24, 26-27 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2005/0096502 to Khalili in view of U.S. Patent No. 5,251,611 to Zehel et al.

**In regards to claim 1**, Khalili discloses an apparatus for obtaining endoluminal access, the apparatus comprising: a flexible elongate body 310 having a working axis and a distal region 308, the elongate body configured for insertion within a body lumen (see paragraphs 0078); at least two working lumens 330, 332 extending through the

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flexible elongate body; at least one articulating element 312-314 disposed near or at the distal region of the elongate body and pivotally connected to the elongate body near or at its distal region by a linkage member 302-304 pivotally connected to a first hinge (not labeled) on the articulating element and a second hinge (not labeled) on the elongate body (see paragraphs 0079-080), wherein the articulating element articulates from an in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening 330 of one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position (see Figs. 1a-b). Khalili disclose that the elongated body the elongated body 4 may be rigid, flexible, or partially flexible depending on the particular application. For example, for laprascopic surgery, it may be desirable to have a rigid elongated body. For insertion into a patient's stomach, the distal section 6 of the elongated body may be rigid, and the proximal section 8 may be flexible so that it can be easily inserted down the esophagus (see paragraph 0048). However, Khalili is silent with respect to the elongate body comprising a plurality of links and at least one tensioning wire whereby the elongate body has a first, substantially flexible state and a second, substantially rigid state. Zehel et al. teach of an analogous apparatus wherein a preferred inner flexible conduit 10 consisting of a plurality of generally cylindrically shaped beads or segments 19 strung on flexible cables 20 passing slidably through the segments 19 by way of a channel 21 bored therein, as best seen in FIG. 3. Alternatively, the cables 20 may be slidably disposed within the segments 19 by means of loops, grooves, or any other means slidably retaining the



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cables 20 at their radial position with respect to the segment, whether the cable is relaxed or flexed (see Figs. 1-3 and Col. 6, Line 40 - Col. 7, Line 50). Furthermore, Zehel et al. teach that the device thus can be an add-on device for an existing endoscope or the stiffening feature may be included in the basic endoscope and one or more segmented concentric devices of the invention may be used around the endoscope (see Col. 10, Lines 20-37). It would have been obvious to one skilled in the art to at the time the invention was made to construct the elongate body of Khalili with a plurality of links and a tensioning wire to create a rigid state in order to provide a stable platform for the deployment of exploratory instruments and thus minimize surgical trauma to the patient and decrease the complexity involved in operating the surgical instruments as taught by Zehel et al.

**In regards to claim 2**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element comprises a visualization element 326 configured to image within a body lumen (paragraph 0079).

**In regards to claim 5**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises at least two articulating elements (see Fig. 13a).

**In regards to claims 6-7**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements are configured for independent off-axis articulation or coordinated off-axis articulation (see paragraphs 0050 and 0054).

**In regards to claims 8-9**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least two articulating elements comprise at least two visualization elements configured to provide stereoscopic visualization (see paragraph 0066).

**In regards to claim 19**, Khalili discloses an apparatus for obtaining endoluminal access, further comprising a visualization element and wherein off-axis articulation of the articulating element is configured to expose the visualization element 330 (see Figs. 1a-d, 8 and 13b).

**In regards to claim 23**, Khalili discloses an apparatus for obtaining endoluminal access further comprising a housing configured to couple the articulating element to the elongate body and to facilitate articulation of the articulating element (see Figs. 13a-b and paragraph 0078).

**In regards to claim 24**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the at least one articulating element is pivotally connected to the elongate body by a pair of pivoting linkage members, with each pair of linkage members being pivotally connected to a first hinge on the articulating element and a second hinge on the elongate body (see Figs. 13a-b and paragraph 0079).

**In regards to claims 26-27**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the elongate body is steerable and may be rigidizable (see paragraphs 0009-0016, 0044-0045, 0048 and 0084-0087).

**In regards to claim 29**, Khalili discloses an apparatus for obtaining endoluminal access, wherein the articulating element further comprises a diagnostic tool (see paragraph 0046, 0066 and 0079).

**In regards to claim 30**, Khalili discloses an apparatus for obtaining endoluminal access, further comprising an atraumatic tip 308 (see paragraph 0078).

#### **(10) Response to Argument**

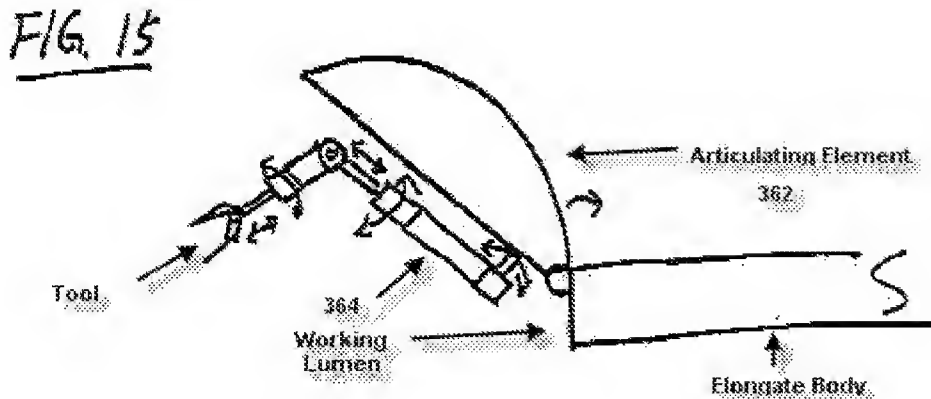
Applicant states that Khalili does not include a “working lumen in the elongate body”. Examiner disagrees. Khalili clearly discloses a “working lumen” which houses the components of therapeutic tool 330. The optical components must be provided within a working lumen. Evidence a “working lumen” must be provided is supported by Khalili teaching that the image detection device (i.e., image detector) may be a camera (e.g., a CCD camera, or an infrared camera), an optical detector, ultrasound detector, or a light sensor array. Alternatively, the chamber 20 may house an optical fiber, allowing light/image capture at the distal end 18 of the elongated body 4 to be directed to the proximal end of the body where an image detector may be implemented to capture the image. Optical lenses may be implemented such that the operator of the device may directly observe actions taking place at the distal end of the device directly (see paragraph 0049). It is noted that the term “working lumen”, may be interpreted as being a fixed camera, as the CCD itself is a “working” element that is provided within a lumen. Additionally, Khalili teaches that the camera is not limited to being a “fixed component”, as it is clearly taught and shown that a separate robotic arm may carry the image detector to provide visual feedback (see paragraph 0066). Specifically, that “an image

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detector 110 is positioned at the distal end 112 of a robotic arm 114, and the position of the image detector may be manipulated by the user". Thus it is fully within the scope of the invention to position camera 330 on a robotic arm which can be extended distal from the elongate housing, as it passes through a working lumen (see, for example, Fig. 7a). Thus, as broadly as claimed, Khalili discloses a "working lumen" in both embodiments; wherein the camera is "fixed" and wherein the camera is carried on a robotic arm. As such, movement of articulating elements 312, 314, 316 to an off-line position will clearly expose the working lumen 330 (see Figs. 13-16).

It is also noted, with regard to Applicant's argument "exemplary grasper tool 90 is shown advanced through lumen 86" as seen in Figure 7 (pg. 14, lines 1-5 of Appeal Brief), that the distal opening of the working lumen 86 *is not* exposed upon movement of articulating element 82a to the out-of-line position.

Alternatively, the embodiment shown in Figure 15 reads on claim 31, wherein it is shown an elongate body having at least one articulating element 362 *disposed near or at* a distal region thereof into a body lumen; moving the articulating element from a position in-line with or adjacent to a working axis of the elongate body to a position out-of-line with the working axis, thereby at least substantially exposing a distal opening of a working lumen 360 provided in the elongate body; and passing a diagnostic or therapeutic tool 368 through the working lumen while the articulating element is maintained in the out-of-line position (see paragraphs 0082). The embodiment shown in Figure 15 also reads upon claims 31 and 65 without interpreting camera 330 as the working lumen as seen below:



As seen in reproduced Figure 15, the “working lumen” may be interpreted as being either the lumen of the elongate body or the lumen of rear-arm 364 which allows for extension/retraction of a therapeutic tool therethrough. In either interpretation, the “working lumen” is exposed upon articulation of element 362 to an out-of-line position and a diagnostic or therapeutic tool is then passed therethrough. It is noted that the Applicant failed to address the interpretation of claim 31 in view of the embodiment shown in Figures 15-16, as presented in the Final Rejection mailed March 11, 2010.

Regarding claims 1 and 65, Applicant states that Khalili does not include a “two working lumens extending through the elongate body”. Examiner disagrees. Khalili clearly discloses at least two working lumens 330, 332, 334 extending through the elongate body.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

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references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one skilled in the art to at the time the invention was made to construct the elongate body of Khalili with a plurality of links and a tensioning wire to create a rigid state in order to provide a stable platform for the deployment of exploratory instruments and thus minimize surgical trauma to the patient and decrease the complexity involved in operating the surgical instruments as taught by Zehel et al.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Primary Examiner, Art Unit 3779  
1/4/11

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